DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

APR 18 2005

Michael J. O'Flaherty
Olsson, Frank and Weeda, P.C.
1400-16th St., N.W., Suite 400
Washington, D.C. 20036-2200

Dear Mr. O'Flaherty:

This is to inform you that the notification you submitted, dated February 1, 2005, on behalf of your client, Shannon Minerals Ltd., pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on February 2, 2005. Your notification concerns the substance that you identify as "synthetically made hydroxycitric acid" ((-)-HCA), which you intend to market as a new dietary ingredient.

According to the notification, you intend to market your proposed new dietary ingredient "synthetically made hydroxycitric acid" in solution form. You state in the notification that "the dietary supplement is a 500 ml solution containing 700 mg (-)- HCA, the dietary ingredient." You indicate that under conditions of use, "the label will recommend use as a dietary supplement by consuming one bottle four times daily (one hour before a meal). It will not be recommended for use by young children or by pregnant or lactating women". In addition, you state that the label will provide a phenylketonurics cautionary statement.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully evaluated the information in your submission and the agency has significant concerns about the evidence upon which you rely to support your conclusion that "synthetically made hydroxycitric acid" when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe.

Your notification fails to clearly identify the new dietary ingredient that you refer to as "synthetically made hydroxycitric acid"; specifically, the information you provided does not identify the distribution of the isomers in the proposed new dietary ingredient "synthetically made hydroxycitric acid".

The notification states that there are a large number of research articles outlining the safety of "synthetically made hydroxycitric acid". The review by Soni et al. (Food and Chemical Toxicology 42: 1513-1529, 2004) states that several placebo-controlled, double blind trials have utilized up to 2800 mg HCA/day. Much of the work reported in this review appears to have been conducted with the preparations (CitriMax™, Super CitriMax™) isolated from the dried rinds of *Garcinia cambogia*. Summaries of studies in humans are also provided in the Soni et al. (2004) review. It is unclear to FDA whether the test substances used in the referenced studies noted above are the same as the "synthetically made hydroxycitric acid" in your notification; the relationship between these materials and the chemically synthesized ingredient that is the subject of the notification is not stated. Therefore, it is not evident that the test substances used in the referenced studies are qualitatively or quantitatively similar to your "synthetically made hydroxycitric acid" or how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

Moreover, since FDA is uncertain about the specific isomers contained in your product, it is unclear how your product, "synthetically made hydroxycitric acid", is a dietary ingredient within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

Based on the information in your submission, it is unclear that "synthetically made hydroxycitric acid" is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1). Therefore, FDA cannot determine, at this time, whether your product is a new dietary ingredient that may lawfully be marketed as a component of a dietary supplement.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "synthetically made hydroxycitric acid" when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of February 2, 2005. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda Pellicore, Ph.D at (301) 436-2375.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
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and Dietary Supplements
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